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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

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3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,623	Applicant(s) WULFMAN ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/09/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 10, 16, 17 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 10, 16, 17 and 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/09/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 2/19-5/19, 2/20-5/20, 10, 16/19, 16/20, 17/19, 17/20, 19, 20, 22/19, 22/20, 23/19, 23/20, 26/19, and 26/20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. (US 5,217,474) in view of Mische et al. (US 5,490,859).**

Regarding claims 19 and 26, Zacca et al. disclose a device having a liquid seal assembly that is capable of using liquid as a sealing medium to prevent air or other fluids from contacting moveable catheter components in the area of a proximal end of a torque tube, the medical device comprising: a torque tube (8) operably connected to a drive system (1) for rotation; a liner (14) surrounding the rotatable torque tube to form a liquid flood space (34) between the liner and the torque tube, wherein the proximal portions of the torque tube and the liner are positioned in a housing (9) in a manner that permits free rotation and axial translation of the torque tube; the liner (14) extending longitudinally less than the axial length of the torque tube and terminating at an intersect area (Fig. 1); an infusion port (3) supplying liquid to the liquid seal assembly at an area of substantially atmospheric pressure (col. 6, ln. 44-46), whereby liquid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area. Zacca et al. fail to disclose an aspiration catheter having a proximal end terminating in the sealing assembly at an aspiration site and extending distally to enclose the torque tube and the liner and beyond the intersect area with respect to the operator, the catheter forming an aspiration lumen between the catheter and the liner. Mische et al. disclose

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an aspiration catheter (90) having a proximal end terminating in a sealing assembly at an aspiration site (port 82) and extending distally to enclose a torque tube (94) having a liner (100; col. 11, ln. 24-35; col. 25, ln. 32-36), Mische et al. further discloses that fluid is provided through the drive shaft and or through the liner (100) and fluid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen. It would have been obvious to one of ordinary skill in the art to modify the medical device of Zacca et al. to include an aspiration catheter having a proximal end terminating in the sealing assembly and extending distally to enclose the torque tube and the liner to form an aspiration lumen between the catheter and the liner as suggested by Mische et al. in order to remove the particulate from the body. Mische et al. disclose the location that fluid exits the liner or the "intersect area" is predetermined by appropriately choosing the length of the liner (100) (col. 25, ln. 32-36). Therefore, it would have been obvious to one of ordinary skill in the art to choose the length of the liner, such that it terminates before the distal end of the aspiration catheter, based on desired location for fluid to exit the liner.

Zacca et al. modified by Mische et al. disclose the liner (14) surrounding the torque tube (8) as it enters an area of high vacuum in the area of the drive system and the aspiration catheter extending distally beyond the intersect area, such that liquid exiting the liner at the intersect area directly enters the aspiration lumen.

Regarding claims 20 and 26, Zacca et al. disclose a medical device comprising: a rotatable torque tube (8) operably connected to a drive system (1) for rotation; a sealing assembly comprising: a housing (9) enclosing at least a proximal portion of the torque tube (8) and a sealing site; a liner (14) surrounding the torque tube (8) and forming a flood space (34) extending from the sealing site along at least a portion of the torque tube to an intersect area; and an infusion port (3) providing application of liquid to the flood space at the sealing site

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during operation of the device (col. 6, ln. 44-46; Fig. 1), whereby during operation of the medical device liquid enters the flood space formed by the liner at the sealing site and creates a liquid seal around the torque tube to prevent ingress of air, the liquid exiting the flood space at the intersect area. Zacca et al. fail to disclose an aspiration catheter terminating in the sealing assembly at an aspiration site and extending distally beyond the intersect area to enclose the liner (14; col. 7, ln. 51-58). Mische et al. disclose an aspiration catheter (90) enclosing a torque tube (94) having a liner (100; col. 11, ln. 24-35; col. 25, ln. 32-36). Mische et al. further discloses that fluid is provided through the drive shaft and or through the liner (100) and fluid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen. It would have been obvious to one of ordinary skill in the art to modify the medical device of Zacca et al. to include an aspiration catheter having a proximal end terminating in the sealing assembly and extending distally to enclose the torque tube and the liner to form an aspiration lumen between the catheter and the liner as suggested by Mische et al. in order to remove the particulate from the body. Mische et al. disclose the location that fluid exits the liner or the "intersect area" is predetermined by appropriately choosing the length of the liner (100) (col. 25, ln. 32-36). Therefore, it would have been obvious to one of ordinary skill in the art to choose the length of the liner, such that it terminates before the distal end of the aspiration catheter, based on desired location for fluid to exit the liner.

Zacca et al. modified by Mische et al. disclose the aspiration catheter extending distally beyond the intersect area, such that liquid exiting the liner at the intersect area directly enters the aspiration lumen.

Regarding claim 2, Zacca et al. disclose the flood space (34) includes a clearance area between the liner and the torque tube.

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Regarding claim 3, Zacca et al. disclose the torque tube is a coiled drive shaft (8) and the flood space includes gaps between the coils.

Regarding claim 4, Zacca et al. disclose the torque tube (8) includes a lumen (64) for a guidewire and the flood space includes the lumen.

Regarding claim 5, Zacca et al. in view of Mische et al. disclose a suction port (82) for aspirating fluid from a lumen and wherein the pressure in the flood space is lower than the pressure outside or proximal to the flood space during operation of the device (col. 25, ln. 61 – col. 26, ln. 4).

Regarding claim 10, Zacca et al. disclose the sealing member further comprises an overflow port for exit of excess liquid and wherein the torque tube extends through the overflow port.

Regarding claim 16, Zacca et al. disclose a drive system (1) coupled to the torque tube to rotate the torque tube.

Regarding claim 17, Zacca et al. disclose a hand held unit (10) and the sealing assembly housed within the hand held unit.

Regarding claim 22, Zacca et al. discloses drive shaft coil with a diameter as small as .032 inches (col. 6, ln. 2), but fail to disclose the inner diameter of the liner. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the diameter of the liner to at least accommodate the drive shaft coil, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 23, Zacca et al. disclose the claimed invention except for the liner length being more than about 6 inches. It would have been obvious to one having ordinary skill

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in the art at the time the invention was made to optimize the length of the liner, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

3. **Claims 21/19, 21/20, 27/19, and 27/20 are rejected under 35 U.S.C. 103(a) as being unpatentable over or over Zacca et al. (US 5,217,474) in view of Mische et al. (US 5,490,859) as applied to claims 19 or 20 above, and further in view of Keith et al. (US 5,938,670).**

Zacca et al. fail to disclose that the pressure within the flood space decreases along the length of the liner in a distal direction during operation of the device and that the length and diameter of the liner forming the flood space are selected to reduce the rate of flow in the proximal to distal direction in the flood space and reduce the requirement for precise diametrical tolerances during operation of the device. Keith et al. disclose that a smaller gap provides more resistance to fluid flow and therefore reduces pressure within a flood space along the length of a liner in a distal direction during the operation of the device in order to prevent significant fluid loss and provide effective cooling of a drive shaft. (col. 12, ln. 11-34). It would have been obvious to one of ordinary skill in the art to dimension the diameter and the length of the liner of Zacca et al. to provide more resistance to fluid flow, thereby reduce pressure within the flood space and reduce the rate of fluid flow along the length of the liner as taught by Keith et al. to provide more effective cooling of the drive shaft coil.

4. **Claims 24/19 and 24/20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. (US 5,217,474) in view of Mische et al. (US 5,490,859) as applied to claims 19 or 20 above, and further in view of Milo (US 6,258,052).**

Zacca et al. is silent as to the material of the liner (14). Milo discloses a polyimide tube in contact with a coiled wire or shaft increases pushability and column strength (col. 2, ln. 61 - col. 3, ln. 2). It would have been obvious to one of ordinary skill to have tried making the liner of

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polyimide tubing to provide the same advantages to the coiled torque tube of Zacca et al. to prevent buckling during operation.

5. Claims 25/19, and 25/20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. (US 5,217,474) in view of Mische et al. (US 5,490,859) and Milo (US 6,258,052) as applied to claim 24 above, and further in view of Machold et al. (US 4,976,720).

Zacca et al. in view of Mische et al. and Milo fail to disclose a lubricious coating. Machold et al. disclose a polyimide tube having a lubricious coating (col. 5, ln. 3-4). It would have been obvious to one of ordinary skill in the art provide a lubricious coating on the polyimide liner to reduce friction between the aspiration catheter and the liner.

Response to Arguments

6. Applicant's arguments with respect to claims 2-5, 10, 16, 17, and 19-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
01/27/2010

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734